

PATENT

Atty. Dkt. No. NEKT/0019

AMENDMENTS TO THE CLAIMS:

Please cancel claims 32-53, add claims 61-82, and amend the claims as follows:

1-53. (Cancelled)

54. (Currently Amended) A method for preparing a coformulation of an active substance and an oligomeric or polymeric material comprising simultaneously dispersing and extracting a fluid vehicle from a solution or suspension of a target substance upon contact with a near-critical or supercritical fluid anti-solvent to induce particle formation, wherein, under the operating conditions used, the active substance is soluble in the ~~chosen~~ anti-solvent ~~[[but]]~~ and the oligomeric or polymeric material is not soluble in the anti-solvent.

55. (Currently Amended) ~~[[A]]~~ The method according to claim 54, wherein the anti-solvent comprises a supercritical fluid.

56. (Currently Amended) ~~[[A]]~~ The method according to claim 55, wherein the anti-solvent is supercritical carbon dioxide.

57. (Currently Amended) ~~[[A]]~~ The method according to any one of claims 54 to 56, wherein the active substance is ketoprofen.

58. (Currently Amended) ~~[[A]]~~ The method according to claim 54, wherein the oligomeric or polymeric material is selected from the group consisting of cellulosic materials, polyvinyl alcohols, polyvinyl chloride, polyvinyl acetates, carboxy vinyl copolymers, poly lactic, polyglycolic acids, ~~[[and]]~~ derivatives thereof, copolymers thereof, and mixtures thereof.

59. (Currently Amended) ~~[[A]]~~ The method according to claim 58, wherein the oligomeric or polymeric material is hydroxypropyl methyl cellulose.

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60. (Currently Amended) A method for preparing a coformulation comprising simultaneously dispersing and extracting a fluid vehicle from a solution or suspension of a target substance upon contact with a near-critical or supercritical fluid anti-solvent to prepare a coformulation of an active substance and an oligomeric or polymeric material, in which between 90 % w/w and 100 % w/w of the active substance is present in an amorphous as opposed to crystalline form, and in which the active substance represents at least 10 % w/w of the coformulation.

61. (New) The method according to claim 60, wherein the anti-solvent comprises a supercritical fluid.

62. (New) The method according to claim 61, wherein the anti-solvent is supercritical carbon dioxide.

63. (New) The method according to claim 60, wherein the active substance is selected from the group consisting of paracetamol, ketoprofen, indomethacin, carbamazepine, theophylline, ascorbic acid, and derivatives thereof.

64. (New) The method according to claim 60, wherein the oligomeric or polymeric material is selected from the group consisting of cellulosic materials, polyvinyl alcohols, polyvinyl chloride, polyvinyl acetates, carboxy vinyl copolymers, poly lactic, polyglycolic acids, derivatives thereof, copolymers thereof, and mixtures thereof.

65. (New) The method according to claim 64, wherein the oligomeric or polymeric material is hydroxypropyl methyl cellulose.

66. (New) A method for preparing a coformulation comprising simultaneously dispersing and extracting a fluid vehicle from a mixture of an active substance and an oligomeric or polymeric material to form particles upon contact with a near-critical or super-critical fluid antisolvent, wherein the particles maintain the active substance

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having an amorphousity within a range from about 90% w/w to about 100% w/w for at least about 18 months.

67. (New) The method according to claim 66, wherein the mixture is a solution, a suspension or a combination thereof.

68. (New) The method according to claim 67, wherein the active substance is selected from the group consisting of paracetamol, ketoprofen, indomethacin, carbamazepine, theophylline, ascorbic acid, and derivatives thereof.

69. (New) The method according to claim 67, wherein the active substance is a COX-2 selective inhibitor.

70. (New) The method according to claim 67, wherein the anti-solvent comprises a supercritical fluid.

71. (New) The method according to claim 70, wherein the anti-solvent is supercritical carbon dioxide.

72. (New) The method according to claim 67, wherein the oligomeric or polymeric material is selected from the group consisting of cellulosic materials, polyvinyl alcohols, polyvinyl chloride, polyvinyl acetates, carboxy vinyl copolymers, poly lactic, polyglycolic acids, derivatives thereof, copolymers thereof, and mixtures thereof.

73. (New) The method according to claim 72, wherein the oligomeric or polymeric material contains hydroxypropyl methyl cellulose.

74. (New) The method according to claim 67, wherein the active substance is a polar substance and the oligomeric or polymeric material is hydrophobic.

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75. (New) The method according to claim 67, wherein 100 % w/w of the active substance is present in an amorphous as opposed to crystalline form.

76. (New) A method for preparing a coformulation comprising paracetamol and an oligomeric or polymeric material by simultaneously dispersing and extracting a fluid vehicle from a solution or suspension of the paracetamol upon contact with a near-critical or supercritical fluid anti-solvent to prepare a coformulation of the paracetamol and the oligomeric or polymeric material, in which between 80 % w/w and 100 % w/w of the paracetamol is present in an amorphous as opposed to crystalline form, and in which the paracetamol represents at least 1 % w/w of the coformulation.

77. (New) The method according to claim 76, wherein the anti-solvent comprises a supercritical fluid.

78. (New) The method according to claim 76, wherein the anti-solvent is supercritical carbon dioxide.

79. (New) The method according to claim 76, wherein the oligomeric or polymeric material is selected from the group consisting of cellulosic materials, polyvinyl alcohols, polyvinyl chloride, polyvinyl acetates, carboxy vinyl copolymers, poly lactic, polyglycolic acids, derivatives thereof, copolymers thereof, and mixtures thereof.

80. (New) The method according to claim 79, wherein the oligomeric or polymeric material is hydroxypropyl methyl cellulose.

81. (New) The method according to claim 79, wherein 100 % w/w of the paracetamol is present in an amorphous form.

82. (New) The method according to claim 79, wherein the paracetamol represents at least 25 % w/w of the coformulation.